according to the location of the drugstore and in accordance with the area of capacity in the workers of ANVISA. **RESULTS:** There were interviewed 105 consumers in drugstores and 140 workers of ANVISA. When asked about the existence of market regulation of drugs, 51.43% and 87.14% of drug users and employees of ANVISA, respectively, said there is regulation of these products. About the PMC, the knowledge was 20.00% of respondents in pharmacies and 57.86% of the employees of ANVISA. Despite of the relative knowledge of PMC, only 01 of the respondents knew where consumers search the PMC, and the employees of ANVISA, 29 knew the sources of research. Although the poor knowledge on the regulation of prices, 84.76% of consumers interviewed considered this activity exerted by the government as important. **CONCLUSIONS:** Although the population consider important that the prices of medicines are regulated by the government, the knowledge of the regulation is small, even on the tools of consumer protection.

PHP121

INSPECTION OF THE PHARMACEUTICAL COMPANIES IN IRAN BY INSPECTION SOFTWARE

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OBJECTIVES: This study was investigating of costs and consequences of two manual and computerized systems for management of information during 2008–2009 for inspection of pharmaceutical industries in Iranian Drug Regulatory Affairs. **METHODS:** To compute costs of processes following items had been considered: Cost of filling and archiving, data collecting (person-hour), reporting (person-hour), transport, software, hardware (main server computer, pocket computer), stationeries. To evaluate the efficacy following outputs and outcomes was considered: Time of information recovering, ability of ranking, preventing of data missing, capacity building and tracking and monitoring. **RESULTS:** The cost of running the new system is 35,000 US Dollars. Cost of education in new method and conventional are 5000 and 1000 US Dollars respectively. Cost of inspection in computerized management of information system (MIS) is decreased to 250 US Dollars from 600 US Dollars for each inspection process. Alongside capacity of system is increased by arming to fast processing method, time of information recovering diminished to 1 working day instead of 3 days, preventing of data missing from 80% to 95% in new one, tracking and monitoring took 7 working days to applied, but new MIS changed that to 1 working day. Ranking of pharmaceutical industries is now available for Iranian Drug Regulatory Affairs after establishment of new inspection system by computer-based MIS. **CONCLUSIONS:** It seems that beside overhead cost of new computerized system that is more than conventional method; considering capacity building; due to decreasing the cost of inspection and increasing of outputs and outcomes indicators, the new system is more efficient.

PHP122

COMPETITIVENESS OF HUNGARY IN INTERNATIONAL CLINICAL TRIALS

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OBJECTIVES: Patients, health service providers, payers and the society also gain from intensive clinical trial participation, however the majority of benefits are intangible. According to a recent survey Hungary generates 0.15% of the GDP from clinical trials and related activities, therefore the economic importance of this area is acknowledged by the Hungarian government. The clinical trial activity is traditionally strong in the country, however the growth rate of clinical trials is lower than in other Central-Eastern European countries. Our objective was to explore how Hungary can improve its competitiveness in attracting clinical trials. **METHODS:** We conducted a literature review, searched for publicly available documents and interviewed key stakeholders in Hungary to explore potential fields for intervention. **RESULTS:** We identified seven key target areas for intervention to improve the competitiveness of Hungary in clinical trials: the simplification of legal framework for clinical trial related activities, development of infrastructure at main potential sites, organizational development with special focus on SMOs, the simplification of rules and processes for financing clinical trials, investment into developing databases to support the set-up of clinical trials, and finally the marketing promotion of Hungary and its sites to sponsors of clinical trials. **CONCLUSIONS:** The area of international clinical trials is a very competitive market. Hungary can strengthen its market position, if legislators, competent authorities and management teams of investigational sites—by acknowledging the professional and financial benefits of these studies—support the successful implementation of clinical trials in coordinated actions.

PHP123

PHARMACY NETWORK DEVELOPMENT DURING ECONOMIC TRANSITION IN POLAND

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OBJECTIVES: To analyze the effects of liberalization of regulations, concerning establishment of pharmacies and pharmacy points in Poland after 1989. **METHODS:** The data on the number of pharmacies and pharmacy points, used for the analysis were collected by mail survey completed by all regional pharmaceutical supervision authorities. Population data were sourced from the statistical yearbook of Poland. **RESULTS:** During economic transition Poland was one of few European Union countries, where the number of pharmacies was not regulated within a given area. Therefore, their numbers increased rapidly, reaching 12.153 private pharmacies and 1.397 private pharmacy points in 2009. This means that in 2009 one pharmacy served 3.127 people. Before privatization process started in 1989, all retail pharmacies were managed by a state-owned enterprise "Cefarm". Since then, the regulations have changed and the number of pharmacies started to grow. The main reasons of this trend was a regulation stipulating that permission to establish a pharmacy can be granted to any private or legal person, disregarding professional education of that person. Pharmacy owner was only required to employ a qualified pharmacist, responsible for managing the pharmacy. Another major institutional change was introduced by the Pharmaceutical Law, voted October 10, 1991, which authorized establishment of pharmacy points. In spite of the general trend, in some poor provinces of Poland the number of pharmacies decreased. June 1, 2010, European Court of Justice ruled that the right to own and operate a pharmacy may be reserved exclusively for pharmacists and that demographic or geographic criteria may be used in the process of issuing permits to operate pharmacies. **CONCLUSIONS:** Currently, the Polish Ministry of Health has to propose amendments to the Pharmaceutical Law, implementing the above mentioned criteria.

PHP124

DESCRIPTION OF THE PRICING AND REIMBURSEMENT SYSTEM IN THE CZECH REPUBLIC

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OBJECTIVES: To investigate changes realized in the Czech pricing and reimbursement system since January 2008 and to describe the current development of this system. **METHODS:** We described the legal framework defining the Czech system (Act No. 48/1997 Coll. as amended by the Act No. 261/2007 Coll. on Public Health Insurance) as well as evaluation of the current system from the literature and reports provided by the State Institute for Drug Control (SUKL). **RESULTS:** In order to increase transparency according to EU Transparency Directive and to set fairly-defined deadlines the competencies for the pricing and reimbursement system were merged from Ministries of Finances and Ministry of Health (MoH) under one responsible institution—SUKL. The pricing rules were fully changed—the maximum price is set based as the mean value of all available ex-factory prices in the reference countries (Estonia, France, Italy, Lithuania, Hungary, Portugal, Greece and Spain). The reference reimbursement system contains 251 reference groups of therapeutically interchangeable products with similar clinical efficacy and safety (should be updated annually by MoH). Medicinal products included in one reference group have the main common therapeutic indication in the same reimbursement level which is calculated on the basis of retail prices in all EU countries. The cheapest price for equipotent dose is chosen and re-counted according to local pharmacy and wholesaler margins and value added taxes. In compliance with new legislation the pharmacoeconomic criteria (cost-effectiveness evaluation and budget impact analysis) should be taken into account. There is possibility of extra bonus of basic reimbursement for better efficacy, safety, dosing schedule, compliance, etc. **CONCLUSIONS:** The system has gone through dramatic changes in last two years and some aspects are still facing challenges. Although the new system should reassessed all medicines covered in the country till 2008, currently there are only 20% revised (April 2010).

HEALTH CARE USE & POLICY STUDIES – Risk-Sharing/Performance-Based Scheme/Agreements

PHP125

TRENDS IN UK-BASED PATIENT ACCESS SCHEMES: FINANCIAL-BASED VERSUS OUTCOMES-BASED AGREEMENTS

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OBJECTIVES: Whilst patient access schemes (PAS) are not a new concept, they are clearly receiving increasing attention. The first notable PAS, devised to improve access to beta interferons for multiple sclerosis, was an outcomes-based scheme designed to overcome uncertainty in long-term clinical and cost-effectiveness. It is the nature of the uncertainty that drives the design of PAS, but is there a trend towards which schemes are more popular? We analyzed the design of published PAS employed in the UK in order to determine if outcomes-based or financial-based schemes predominate. **METHODS:** Published PAS were identified from health technology assessment websites (e.g. the National Institute for Health and Clinical Excellence and Scottish Medicines Consortium), literature searching of ISPOR conference abstracts, and searching of 'patient access scheme' or 'risk-sharing scheme,' using internet search engines. PAS identified were categorised as financial-based (price- or volume-based agreements) or outcomes-based schemes. Desk research was the performed to identify the preference for each type of scheme, in terms of uptake by UK Primary Care Trusts. **RESULTS:** Seventeen published PAS were identified from the literature search, from 2002 until 2010. Categorization of PAS as financial-based versus outcomes-based showed that schemes were balanced, but favoured financial-based schemes (59% versus 41%, respectively). The uptake of financial-based schemes was found to be higher than outcomes-based schemes due to administrative burden posed by schemes which rely